JUN 1 8 2001

K010870

LAP DISC Hand Access Device
510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Dennis Hahn
Manager, Regulatory Affairs

Date Prepared:
March 22, 2001

Name of Device
Trade Name: LAP DISC Hand Access Device
Classification Name: Laparoscope, General & Plastic Surgery

Predicate Devices:
Dexterity Pneumosleeve Set, cleared under K962147 on 07/09/96.
Intromit Hand Access Port, cleared under K990663 on 05/27/99.
Smith & Nephew Handport System, cleared under K990414 on 04/14/99.

Device Description
The LAP DISC is a sterile, single-use disposable device. The LAP DISC is an abdominal wall closure unit consisting of three overlaid plastic rings that are interconnected by means of a silicone rubber. The two lower rings hold the abdominal wall to maintain peritoneal gas pressure. The bottom ring is a flexible ring made with a shape-memory alloy. The top ring has a structure similar to the aperture in a camera (an Iris Valve). Because the aperture of the Iris Valve can be adjusted continuously, the system can maintain constant peritoneal gas pressure while allowing the insertion of the surgeon's hand and alternatively, it can be used as an insertion site.

Intended Use
The LAP DISC Hand Access Device is intended to provide extracorporeal extension of pneumoperitoneum and abdominal access for the surgeon during laparoscopic surgery. The LAP DISC is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens. The LAP DISC has application in colorectal, urological and general surgical procedures. This indication for use includes the specific procedures which fall under these broad categories.

Technological Characteristics

The LAP DISC Hand Access Device is similar to the predicate devices in that it has the same intended use and is a single use sterile device. The incision size required to place the LAP DISC Hand Access Device is approximately equal to the glove size of the surgeon's hand, which is the same requirement for the predicate devices. The LAP DISC Hand Access Device is different from the predicate devices in that is a single piece design and does not require an adhesive to maintain a seal with the patient's body wall.

Performance Data

Preclinical testing was performed to ensure the device performs as intended when used according to the instructions for use. Bench and animal testing demonstrated satisfactory performance of the LAP DISC Hand Access Device during laparoscopic surgical procedures. Clinical articles are provided which support the performance of the device in human laparoscopic surgical procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Dennis Hahn
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K010870
Trade/Device Name: LAP DISC Hand Access Device
Regulation Number: 876.1500
Regulatory Class: II
Product Code: GCJ
Dated: May 09, 2001
Received: May 10, 2001

Dear Mr. Hahn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010870

Device Name: LAP DISC Hand Access Device

Indications for Use:

The LAP DISC Hand Access Device is intended to provide extracorporeal extension of pneumoperitoneum and abdominal access for the surgeon during laparoscopic surgery. The LAP DISC is indicated for use in laparoscopic procedures, where entry of the surgeon's hand may facilitate the procedure, and for extraction of large specimens. The LAP DISC has application in colorectal, urological and general surgical procedures. This indication for use includes the specific procedures which fall under these broad categories.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010870

(Optional Format 3-10-98)